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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,809	06/27/2003	Leonard Katz	300622004810	6321

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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1656

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/607,809

Applicant(s)

KATZ ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/15/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election without traverse of Group I (claims 1-2) on January 1, 2006 is acknowledged.
2. Claims 1-6 are pending. Claims 1-2 are under examination. Claims 3-6 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.
3. The Amendment filed on October 24, 2003 has been received and entered.

### ***Specification***

4. The specification is objected to because of the following informalities:
  - (a) The specification is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 35 for example. It is suggested that http:// is deleted.
  - (b) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "Polyketide Genes and the Production of Polyketides".

Correction is required.

***Abstract***

5. The Abstract is objected to because of the following informalities:

In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the genes and the source of the genes, (i.e. *ccr* gene obtained from *Streptomyces collinus* and the domains that must be present (i.e. KSQ, AT specific for ethylmalonyl CoA and ACP domains) for completeness.

Correction is required.

***Drawing***

6. The drawings filed on October 23, 2004 have been accepted.

***Claim Objection***

7. Claim 2 is objected to because of the following informalities:

Claim 2 is objected to because the acronyms "ccr" and "icm" appears in the claims without the spelled out meaning.

Correction is required.

***Information Disclosure Statement***

8. The Information Disclosure Statement filed on December 15, 2003 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. However, note that references by Khosla, Liu, Pfeifer, Pieper, Stassi, Tange, Vrijbloed, Wallace and Xue have been lined through because a copy was not found in the parent file.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

9. Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 2 is drawn to a host cell, which reads on a product of nature. The claims should be amended to indicate the hand of the inventor, for example the insertion of recombinant, isolated or purified in connection with the host cell to identify a product not found in nature (see MPEP 2105).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a recombinant polyketide synthase gene and host cell comprising same. The claims are described by functional properties, not by structural properties *per se*. It is noted that the specification provides specific sequences, however, none is recited in the claims. For example, claim 2 recites *ccr* and *icm* genes and the claim does not set forth whether the *ccr* gene is derived from *Streptomyces collinus* or *Streptomyces coelicolor* for example, or provide a structure that corresponds to the genes. In addition, the art recognizes *icmA* and *icmb*, however, the claims do not delineate the specific gene referred to. Therefore, the skilled artisan cannot envision the detailed chemical structure encompassed in the claims.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966

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(*Fed. Cir. 1997*). Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. See *MPEP 2163*.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kuhstoss et al. (Gene, vol. 183, pages 231-236, 1996), cited on IDS.

The claimed invention is directed to a recombinant polyketide synthase (PKS) gene encoding a loading module comprising a KSQ domain, an AT specific for ethylmalonyl CoA and an ACP domain. Kuhstoss et al. teach PKS genes containing

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modules such as a starter module (equivalent to a loading module), see page 231 of the reference. The starter module of the reference has a KS<sup>Q</sup>, AT and ACP domain (see Figure 1 of the reference). Furthermore, Kuhstoss et al. teach that the AT domains in PKS type I systems select the appropriate substrate at each step in the synthesis.

Therefore, the limitations of the claim is met by the reference.

### ***Basis For NonStatutory Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6 and 10-12 of U.S. Patent No. 6,627,427. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim is directed to a recombinant polyketide synthase gene that encodes a loading module comprising a KSQ domain, an AT-specific for ethylmalonyl CoA domain and an ACP domain. The instant invention is also directed to a host cell comprising the recombinant polyketide synthase gene further comprising recombinant ccr and icm genes.

The patented claims are directed a recombinant host cell (*S. erythraea*) comprising an expression vector for a ccr gene from *Streptomyces collinus* or *streptomyces coelicolor*. The patented host cell has a KS domain of a modular polyketide synthase, an ethylmalonyl-specific AT domain and an ACP domain designated KSQ-emAT-ACP. The patented host cell further comprises a recombinant icmA and icmB genes. The two sets of claims differ in that the patented claims are

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directed to the host cell and the instant application is directed to the gene and host cell. Note that the gene and host cell goes hand in hand, in fact the patented claims to the host cell encompasses and recites the gene (i.e. claim 1 vector for ccr gene). Both sets of claims encompass the same domains and are directed to the ccr gene and icm genes.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the same material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, to recite that the genes are obtained from *Streptomyces collinus* or *ceolicolor* and to recite recombinant host cell and to recite *icmA/icmB* as disclosed in the instant specification and recited in the species set forth in the patent as the instant claims are a genus over the patented claims; and the species language would clarify the claims by providing the specific species. Thus, the copending claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

This is an obvious-type double patenting rejection.

### **Conclusion**

14. No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

**HOPE ROBINSON**  
**PATENT EXAMINER**

3/9/06